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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/411,797	10/01/1999	STEVE A. HERWECK	ATA-257	8813

959 7590 03/27/2002

LAHIVE & COCKFIELD  
28 STATE STREET  
BOSTON, MA 02109

EXAMINER
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LAM, ANN Y

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 03/27/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/411,797

Applicant(s)

HERWECK ET AL. *CH*

Examiner

Ann Y. Lam

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 January 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-27 and 44-52 is/are pending in the application.
- 4a) Of the above claim(s) 28-43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-27 and 44-52 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 4, 6-20, 24-27 and 44 are rejected under 35 U.S.C. 102(b) as being anticipated by Kaplan et al., 5,336,178, for the same reasons as described in Office action dated June 16, 2001.

Claims 1-4, 6-10, 13-20, 24-27 and 44-49 are rejected under 35 U.S.C. 102(b) as being anticipated by Butler et al., 5,843,069, for the same reasons as described in Office action dated June 16, 2001.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5, 21-23, and 50-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Butler et al., 5,843,069, for the same reasons as described in Office action dated June 16, 2001.

***Response to Arguments***

Applicant's arguments filed January 9, 2002 have been fully considered but they are not persuasive.

Applicant argues that Kaplan does not disclose a member having a microstructure of nodes interconnected by fibrils, wherein the wall of the member includes at least one microporous portion having a porosity sufficient for a fluid to permeate through the wall, and wherein the nodes are oriented such that spaces between the nodes form micro-channels extending from the inner surface to the outer surface of the wall, see page 6, lines 17-22. Examiner however reasserts that Kaplan discloses a member (28 and 32), wherein the area between the orifices (34) constitute the nodes, as claimed. Moreover, the nodes are oriented such that spaces between the nodes form micro-channels extending from the inner surface to the outer surface of the wall, see column 7, lines 35-37.

Applicant also argues that Butler does not disclose a single wall inflatable member, but rather a two piece apparatus, see page 8, lines 13-19, and page 9, lines 14-15. In response, Examiner asserts that Butler discloses all the elements of Applicant's claims. More specifically, Butler discloses a first layer and a second layer of biocompatible material, as claimed, see column 8, line 66 – column 9, line 5 of Butler.

Applicant also argues that Butler describes an implantable housing that supports a drug delivery device, whereas Applicant's claimed invention is a drug delivery device

Art Unit: 3763

that does not require an implanted housing for operation, see page 8, lines 24-26. In response, Examiner asserts that Butler discloses all the elements as claimed, and that it is irrelevant that Butler discloses that the disclosed device is implantable, so long as Butler discloses all of Applicant's claimed elements.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is (703) 306-5560. The examiner can normally be reached on T-F 8-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (703)308-3552. The fax phone numbers for


Application/Control Number: 09/411,797


Page 5

Art Unit: 3763

the organization where this application or proceeding is assigned are (703)305-3590 for regular communications and (703)306-4520 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0858.

A.L.   
March 25, 2002

  
ANH TUAN T. NGUYEN  
PRIMARY EXAMINER  
3/25/02

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-27 and 44-52, drawn to a radially expandable fluid delivery device, classified in class 604, subclass 264.
  - II. Claims 28-43, drawn to a method of making the radially expandable fluid delivery device, classified in class 264, subclass 127.
2. The inventions are distinct, each from the other because of the following reasons:

Inventions of Group II and Group I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product as claimed could be made by another and materially different method wherein a preformed tube made by a method other than extrusion, e.g. forming a tube by welding or stitching two ends of a flat sheet of fluoropolymer, is expanded by applying a radial expansion force from an initial diameter to a second diameter.
3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.
4. During a telephone conversation with applicant's attorney Kevin Canning on April 2, 2001, a provisional election was made with traverse to prosecute the invention of Group I, claims 1-27 and 44-52. Affirmation of this election must be made by applicant in replying to this Office action. Claims 28-43 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.
5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of

Art Unit: 1732

inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).